WHAT IS CLAIMED IS:

1. Form H crystalline eplerenone having an orthorhombic crystal system and an X-ray powder diffraction pattern with a peak at 12.0 ± 0.2 degrees 2θ.

2. The crystalline eplerenone of Claim 1 having a melting point in a range from about 247°C to about 251°C.

3. The crystalline eplerenone of Claim 1 in the form of particles having a D_{90} particle size less than about 400 μm.

4. The crystalline eplerenone of Claim 1 in the form of particles having a D_{90} particle size of about 25 to about 400 μm.

5. The crystalline eplerenone of Claim 1 in the form of particles having a D_{90} particle size of about 0.01 to about 15 μm.

6. An eplerenone drug substance comprising Form H crystalline eplerenone in a detectable amount.

7. The eplerenone drug substance of Claim 6 comprising about 90% to about 100% of Form H crystalline eplerenone.

8. The eplerenone drug substance of Claim 6 that is substantially phase pure Form H crystalline eplerenone.

9. The eplerenone drug substance of Claim 6 wherein the balance of the eplerenone consists of one or more of (i) Form L crystalline eplerenone having a monoclinic crystal system, (ii) a solvated crystalline form of eplerenone and (iii) amorphous eplerenone.

10. A pharmaceutical composition comprising the crystalline eplerenone of Claim 1 in a therapeutically effective amount of about 10 to about 1000 mg, and one or more pharmaceutically acceptable excipients.

11. A pharmaceutical composition comprising an eplerenone drug substance of Claim 6 in a therapeutically effective amount of about 10 to about 1000 mg, and one or more pharmaceutically acceptable excipients.

12. A method of treating or preventing an aldosterone-mediated condition or disorder, the method comprising administering to a subject having or susceptible

to such condition or disorder a therapeutically or prophylactically effective amount of the composition of Claim 10.

13. A method of treating or preventing an aldosterone-mediated condition or disorder, the method comprising administering to a subject having or susceptible to such condition or disorder a therapeutically or prophylactically effective amount of the composition of Claim 11.

14. A process for preparing the Form H crystalline eplerenone of Claim 1, the process comprising crystallizing eplerenone from a high boiling solvent or a mixture of solvents comprising a high boiling solvent, at a temperature above the enantiotropic transition temperature for Form H crystalline eplerenone.

15. The process of Claim 14 wherein the solvent or mixture of solvents is seeded with crystals of Form H eplerenone prior to crystallizing the eplerenone.

16. A process for preparing an eplerenone drug substance of Claim 6, the process comprising crystallizing eplerenone from a high boiling solvent or mixture of solvents comprising a high boiling solvent, at a temperature above the enantiotropic transition temperature for Form H eplerenone.

17. The process of Claim 16 wherein the solvent or mixture of solvents is seeded with crystals of Form H eplerenone prior to crystallizing the eplerenone.

18. A process for preparing the Form H crystalline eplerenone of Claim 1, the process comprising

(a) crystallizing eplerenone from a solvent or mixture of solvents to form a solvate; and

(b) desolvating the solvate.

19. The process of Claim 18 wherein the solvent or mixture of solvents comprises a solvent selected from the group consisting of methyl ethyl ketone, 2-pentanone, acetic acid, acetone, butyl acetate, chloroform, ethanol, isobutanol, isobutyl acetate, methyl acetate, ethyl propionate, n-butanol, n-octanol, n-propanol, isopropanol, propyl acetate, propylene glycol, t-butanol, tetrahydrofuran, toluene and t-butyl acetate.

20. The process of Claim 18 wherein the solvent or mixture of solvents comprises methyl ethyl ketone or ethanol.

21. A process for preparing an eplerenone drug substance of Claim 6, the process comprising

(a) crystallizing eplerenone from a solvent or mixture of solvents to form a solvate; and

(b) desolvating the solvate.

22. The process of Claim 21 wherein the solvent or mixture of solvents comprises a solvent selected from the group consisting of methyl ethyl ketone, 2-pentanone, acetic acid, acetone, butyl acetate, chloroform, ethanol, isobutanol, isobutyl acetate, methyl acetate, ethyl propionate, n-butanol, n-octanol, n-propanol, isopropanol, propyl acetate, propylene glycol, t-butanol, tetrahydrofuran, toluene and t-butyl acetate.

23. The process of Claim 21 wherein the solvent or mixture of solvents comprises methyl ethyl ketone or ethanol.

24. A solvated crystalline form of eplerenone that can be desolvated to yield Form H eplerenone.

25. The solvated crystalline form of Claim 24 selected from the group consisting of methyl ethyl ketone, 2-pentanone, acetic acid, acetone, butyl acetate, chloroform, ethanol, isobutanol, isobutyl acetate, methyl acetate, ethyl propionate, n-butanol, n-octanol, n-propanol, isopropanol, propyl acetate, propylene glycol, t-butanol, tetrahydrofuran, toluene and t-butyl acetate solvates.

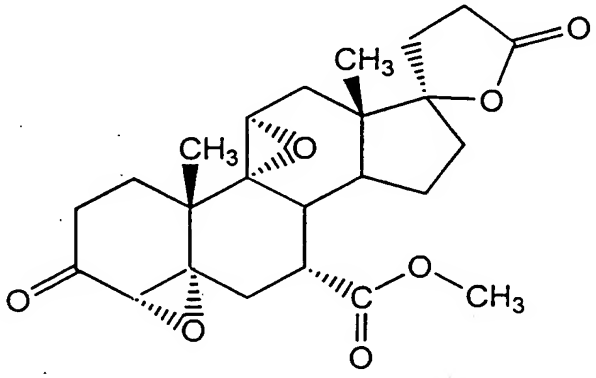
26. Amorphous eplerenone.

27. The amorphous eplerenone of Claim 26 that is substantially free of crystalline eplerenone.

28. A method for promoting crystallization of Form H eplerenone from a solution of eplerenone in a solvent or mixture of solvents, the method comprising doping the solution prior to crystallization with an effective amount of a dopant compound that is crystallographically substantially isostructural to Form H eplerenone.

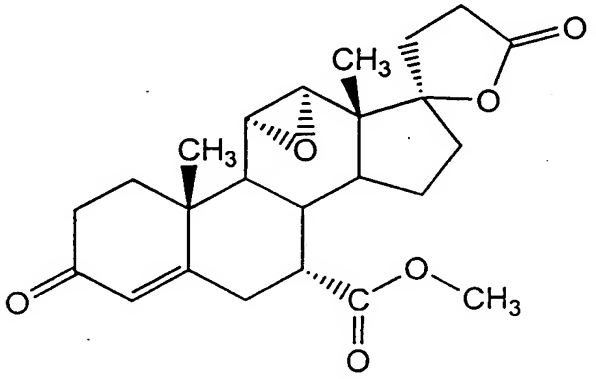
29. The method of Claim 28 wherein the dopant compound is selected from the group consisting of 7-methyl hydrogen 4α,5α;9α,11α-diepoxy-17 hydroxy-3-oxo-17α-pregnane-7α,21-dicarboxylate, γ-lactone; 7-methyl hydrogen 11α,12α-epoxy-17-hydroxy-3-oxo-17α-pregn-4-ene-7α,21-dicarboxylate, γ-lactone; and 7-methyl hydrogen 17-hydroxy-3-oxo-17α-pregna-4,9(11)-diene-7α,21-dicarboxylate, γ-lactone.

30. A compound useful as a dopant in promoting crystallization of Form H eplerenone from a solution, the compound having the formula



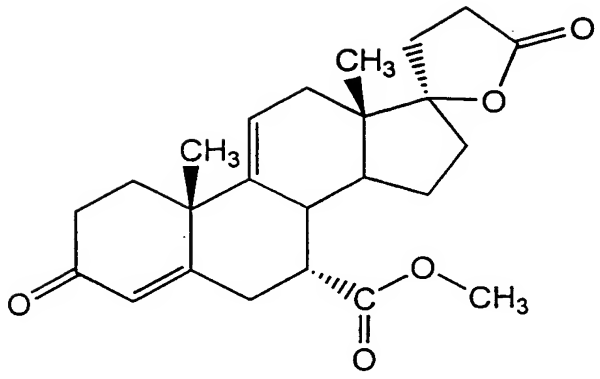
(7-methyl hydrogen 4α,5α;9α,11α-diepoxy-17 hydroxy-3-oxo-17α-pregnane-7α,21-dicarboxylate, γ-lactone).

31. A compound useful as a dopant in promoting crystallization of Form H eplerenone from a solution, the compound having the formula



(7-methyl hydrogen 11α,12α-epoxy-17-hydroxy-3-oxo-17α-pregn-4-ene-7α,21-dicarboxylate, γ-lactone).

32. A compound useful as a dopant in promoting crystallization of Form H eplerenone from a solution, the compound having the formula



(7-methyl hydrogen 17-hydroxy-3-oxo-17α-pregna-4,9(11)-diene-7α,21-dicarboxylate, γ-lactone).